



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/551,877

09/14/2006

Jose Francisco Rodriguez Aguirre

7572-73331-01

3916

24197 7590 03/05/2008

KLARQUIST SPARKMAN, LLP
121 SW SALMON STREET
SUITE 1600
PORTLAND, OR 97204

EXAMINER

HILL, KEVIN KAI

ART UNIT

PAPER NUMBER

1633

MAIL DATE

DELIVERY MODE

03/05/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/551,877	AGUIRRE ET AL.	
	Examiner	Art Unit	
	KEVIN K. HILL	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-38 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, Applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, Claims 1-7, 9-12 and 14-17, drawn to:

- a) a gene construct comprising (i) a nucleotide sequence comprising the open reading frames corresponding to the polyprotein of the infectious bursal disease virus (BDV) operatively bound to a nucleotide sequence comprising a first promoter, and (ii) a nucleotide sequence comprising the open reading frame corresponding to the IBDV VP1 protein operatively bound to a nucleotide sequence comprising a second promoter, wherein the said first promoter and second promoter are different promoters,
- b) an expression system comprising said first gene construct, and
- c) a host cell transformed or transfected with said gene construct.

Group II, Claims 10-12 and 14-17, drawn to:

- a) an expression system comprising a first gene construct comprising a nucleotide sequence comprising the open reading frames corresponding to the polyprotein of the infectious bursal disease virus (BDV) operatively bound to a nucleotide sequence comprising a first promoter, and a second gene construct comprising a nucleotide sequence comprising the open reading frame corresponding to the IBDV VP1 protein operatively bound to a nucleotide sequence comprising a second promoter, wherein the first and second gene constructs are encoded in the same nucleic acid, and wherein the first and second promoters are the same,
- b) an expression system comprising said first and second gene constructs, and
- c) a host cell transformed or transfected with said gene constructs.

Art Unit: 1633

Group III, Claims 9-12 and 14-17, drawn to:

- a) an expression system comprising a first gene construct comprising a nucleotide sequence comprising the open reading frames corresponding to the polyprotein of the infectious bursal disease virus (BDV) operatively bound to a nucleotide sequence comprising a first promoter, and a second gene construct comprising a nucleotide sequence comprising the open reading frame corresponding to the IBDV VP1 protein operatively bound to a nucleotide sequence comprising a second promoter, wherein the first and second gene constructs are encoded in separate nucleic acid molecules, and wherein the first and second promoters are different promoters,
- b) an expression system comprising said first and second gene constructs, and
- c) a host cell transformed or transfected with said gene constructs.

Group IV, Claims 10-12 and 14-17, drawn to:

- a) an expression system comprising a first gene construct comprising a nucleotide sequence comprising the open reading frames corresponding to the polyprotein of the infectious bursal disease virus (BDV) operatively bound to a nucleotide sequence comprising a first promoter, and a second gene construct comprising a nucleotide sequence comprising the open reading frame corresponding to the IBDV VP1 protein operatively bound to a nucleotide sequence comprising a second promoter, wherein the first and second gene constructs are encoded in separate nucleic acid molecules, and wherein the first and second promoters are the same,
- b) an expression system comprising said first and second gene constructs, and
- c) a host cell transformed or transfected with said gene constructs.

Group V, Claims 21-23, drawn to a process for the production of whole empty viral capsids of IBDV, the method comprising the use of a gene construct comprising (i) a nucleotide sequence comprising the open reading frames corresponding to the polyprotein of the infectious bursal disease virus (BDV) operatively bound to a nucleotide sequence comprising a first promoter, and (ii) a nucleotide sequence comprising the open reading frame corresponding to the IBDV VP1 protein operatively

Art Unit: 1633

bound to a nucleotide sequence comprising a second promoter, wherein the said first promoter and said second promoter are different promoters.

Group VI, Claim 22, drawn to a process for the production of whole empty viral capsids of IBDV, the method comprising the use of an expression system comprising a first gene construct comprising a nucleotide sequence comprising the open reading frames corresponding to the polyprotein of the infectious bursal disease virus (BDV) operatively bound to a nucleotide sequence comprising a first promoter, and a second gene construct comprising a nucleotide sequence comprising the open reading frame corresponding to the IBDV VP1 protein operatively bound to a nucleotide sequence comprising a second promoter, wherein the first and second gene constructs are encoded in the same nucleic acid, and wherein the first and second promoters are the same.

Group VII, Claims 24-25, drawn to a process for the production of whole empty viral capsids of IBDV, the method comprising the use of an expression system comprising a first gene construct comprising a nucleotide sequence comprising the open reading frames corresponding to the polyprotein of the infectious bursal disease virus (BDV) operatively bound to a nucleotide sequence comprising a first promoter, and a second gene construct comprising a nucleotide sequence comprising the open reading frame corresponding to the IBDV VP1 protein operatively bound to a nucleotide sequence comprising a second promoter, wherein the first and second gene constructs are encoded in separate nucleic acid molecules, and wherein the said first promoter and said second promoter are different promoters.

Group VIII, Claim 25, drawn to a process for the production of whole empty viral capsids of IBDV, the method comprising the use of an expression system comprising a first recombinant baculovirus comprising a gene construct comprising a nucleotide sequence comprising the open reading frames corresponding to the polyprotein of the infectious bursal disease virus (BDV) operatively bound to a nucleotide sequence comprising a first promoter, and a second recombinant baculovirus comprising a gene construct comprising

Art Unit: 1633

a nucleotide sequence comprising the open reading frame corresponding to the IBDV VP1 protein operatively bound to a nucleotide sequence comprising a second promoter, wherein the first and second gene constructs are encoded in separate nucleic acid molecules, and wherein the first and second promoters are the same.

Group IX, Claims 26-29, 31-34, drawn to a vaccine composition comprising whole empty capsids of the of the infectious bursal disease virus (IBDV), containing the VPX, VP2, VP3 and VP1 proteins of IBDV, and a method of combating avian infectious bursal disease, comprising administering to an avian subject said vaccine.

Group X, Claim 30, drawn to a gene therapy vector and whole empty whole empty capsids of the of the infectious bursal disease virus (IBDV) containing the VPX, VP2, VP3 and VP1 proteins of IBDV.

Group XI, Claims 35-38, drawn to a process for obtaining a dual recombinant baculovirus allowing simultaneous expression in insect cells of the polyprotein of the infectious bursal disease virus (IBDV) and of the IBDV VP1 protein from two independent open reading frames, wherein each open reading frame is controlled by a different baculovirus promoter.

Claims 8 and 13 link Groups I-IV.

Claim 18 links Groups I and III.

Claims 19 and 20 link Groups V-VIII.

2. The inventions listed as Groups I-XI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical feature for the following reasons:

37 CFR 1.475(c) states:

"If an application contains claims to more or less than one of the combinations of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present."

37 CFR 1.47(d) also states:

"If multiple products, processes of manufacture, or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each of the other categories related thereto will be considered as the main invention in the claims, see PCT article 17(3)(a) and 1.476(c). "

A 371 case is considered to have unity of invention only when there is a technical relationship among those inventions involving one or more of the same or corresponding technical features. The expression "special technical feature" means those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. In the instant application, the International Search Report has determined that "hitherto a great number of IBDV VLPs have been described in the prior art", and correspondingly, claims relating to such capsids cannot be considered to be novel, i.e. claims 26-27 and 31-34." Similarly, claims 20 and 22 lack novelty as they related to expression systems wherein the first and second promoters are identical.

The special technical feature of Group I, is a gene construct wherein the first promoter regulating expression of a first protein-coding polynucleotide is different than the second promoter regulating expression of a second protein-coding polynucleotide, wherein the first and second protein-coding polynucleotides are different. The special technical feature of Group II, is a gene expression system comprising a first gene construct and a second gene construct, wherein the first and second promoters are the same. The special technical feature of Group III is a first nucleic acid molecule distinctly different and separate from the second nucleic acid molecule, wherein the first and second promoters are different. The special technical feature of Group IV is a first nucleic acid molecule distinctly different and separate from the second nucleic acid molecule, wherein the first and second promoters are the same. The special technical feature of Group VII is a dual recombinant baculovirus; whereas Groups V-VI, may be an enormous genus

Art Unit: 1633

of gene expression vectors (claim 12). The special technical feature of Group VIII is a first and second recombinant baculovirus. The special technical feature of Group IX not present in the other Groups is a vaccine composition comprising whole empty IBDV capsids and a method of vaccinating avians. The recitation of a process limitation in claim 26 is not viewed as positively limiting the claimed product absent a showing that the process of making recited in claim 20 imparts a novel or unexpected property to the claimed product, as it is assumed that equivalent products are obtainable by multiple routes. The burden is placed upon the Applicants to establish a patentable distinction between the claimed and referenced products. The special technical feature of Group X not present in the other Groups is a gene therapy vector. The special technical feature of Group XI not present in the other Groups is a method of making a dual recombinant baculovirus.

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

- (a) the inventions have acquired a separate status in the art in view of their different classification;
- (b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;
- (c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);
- (d) the prior art applicable to one invention would not likely be applicable to another invention;
- (e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

Art Unit: 1633

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, Applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, Applicant must indicate which of these claims are readable upon the elected invention.

Should Applicant traverse on the ground that the inventions are not patentably distinct, Applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the Examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The Examiner has required restriction between product and process claims. Where Applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be

Art Unit: 1633

amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the Examiner before the patent issues. See MPEP § 804.01.

Claims 8 and 13 link Groups I-IV. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), Claims 8 and 13.

Claim 18 links Groups I and III. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), Claim 18.

Claims 19 and 20 link Groups V-VIII. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), Claims 19 and 20.

Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104. Claims that require all the limitations of an allowable linking claim will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim(s) including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

3. **Should Applicant elect any of Groups I-VIII, a species restriction is required under 35 U.S.C. 121 and 372.** This application contains claims, Claims 8-10, 13, 19, 24-25, directed to more than one species of gene constructs comprising regulatory elements. These species are deemed to lack unity of invention because they are not so linked as to form a single general

Art Unit: 1633

inventive concept under PCT Rule 13.1. In response to the restriction requirement, Applicant must further elect a single gene construct species, specifically:

- i) wherein the gene construct comprises translation control elements, or
- ii) wherein the gene construct does not comprise translation control elements.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

The species are drawn to multiple gene constructs that are structurally distinct. The translation control elements confer a unique, non-obvious, distinctly different technical feature onto the gene constructs that will directly impact the expression of the viral polypeptides in the host cell.

Applicant is required to elect a single named gene construct species as listed in the cited claims to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Should Applicant elect any of Groups I-IV, a species restriction is required under 35 U.S.C. 121 and 372. This application contains claims, Claim 12, directed to more than one species of expression systems. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1. In response to the restriction requirement, Applicant must further elect a single expression system from the list consisting of the expression systems recited in Claim 12.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

The species are drawn to multiple expression systems that are structurally distinct. The systems are not obvious variations of each other because one skilled in the art does not expect a

Art Unit: 1633

yeast artificial chromosome to be packaged into a virus as a viral vector, or to yield efficient gene expression in bacteria as a plasmid.

Because these inventions are distinct for reasons given above, and because a search of one does not necessarily overlap with that of another, it would be unduly burdensome for the Examiner to search and examine all the subject matter being sought in the presently pending claims and thus, restriction for examination purposes as indicated is proper. Given the breadth of the claimed, unrelated structures, a search for all possible vector species imposes an exceptional burden on the Office. As the technical feature of IBDV VLPs linking the members do not constitute a special technical feature as defined by PCT Rule 13.2, particularly since each of the species does not share a substantially common structural feature or function, the requirement for unity of invention is not fulfilled.

Applicant is required to elect a single named vector species as listed in the cited claims to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

The claims are deemed to correspond to the species listed above in the following manner:

Claim 8, and claims dependent therefrom correspond to all the species listed above. The following claim(s) are generic: Claim 8.

Should Applicant elect any of Groups I-VII a species restriction is required under 35 U.S.C. 121 and 372. This application contains claims directed to more than one species of host cells. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1. In response to the restriction requirement, Applicant must further elect a single host cell species, specifically:

- i) bacteria, as recited in Claim 15,
- ii) insect cells, as recited in Claims 17 and 23,
- iii) bird cells, as recited in Claim 17, or
- iv) mammal cells, as recited in Claim 17.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

The species are drawn to multiple host cells that are structurally distinct. Each of the host cells species comprises distinctly different gene expression regulatory mechanisms that necessitate non-obvious and distinctly different technical features onto the gene expression construct(s) for optimal expression of the desired viral polypeptides. Given the breadth of the claimed, unrelated structures, a search for all possible species at each of the recited host cells imposes an exceptional burden on the Office. A search for bacteria would not be co-extensive with a search for a mammalian cell. Further, a reference rendering bird cells as anticipated or obvious over the prior art would not necessarily also render insect cells as anticipated or obvious over the prior art. Similarly, a finding that bacteria was novel and unobvious over the prior art would not necessarily extend to a finding that mammalian cells are also novel and unobvious over the prior art. Because these inventions are distinct for reasons given above, and because a search of one does not necessarily overlap with that of another, it would be unduly burdensome for the Examiner to search and examine all the subject matter being sought in the presently pending claims and thus, restriction for examination purposes as indicated is proper. As the technical feature of IBDV VLPs linking the members do not constitute a special technical feature as defined by PCT Rule 13.2, particularly since each of the species does not share a substantially common structural feature or function, the requirement for unity of invention is not fulfilled.

Applicant is required to elect a single named host cell species as listed in the cited claims to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

The claims are deemed to correspond to the species listed above in the following manner:

Claims 13-14, and claims dependent therefrom correspond to all the species listed above. The following claim(s) are generic: Claim 13-14.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, Applicant must indicate which of these claims are readable on the elected species.

Should Applicant traverse on the ground that the species are not patentably distinct, Applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the Examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, Applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, Applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should Applicant add or amend the claims of the elected invention to introduce subject matter from a non-elected invention for which the above stated group restriction(s) and/or

Art Unit: 1633

species election(s) is(are) required, then Applicant is required to make the appropriate elections set forth above in accordance with the subject matter recited in the newly added or amended claims.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Kevin K. Hill, Ph.D. whose telephone number is 571-272-8036. The Examiner can normally be reached on Monday through Friday, between 9:00am-6:00pm EST.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Joseph T. Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kevin K. Hill, Ph.D./

Examiner, Art Unit 1633

/Q. JANICE LI/

Primary Examiner, Art Unit 1633